REMARKS:

Applicants express gratitude to the Examiner for the withdrawal of the rejections under 35 U.S.C. § 102(b) as being anticipated by Raaf et al. (U.S. 4,397,837) and the telephone interview conducted on March 21, 2011.

Applicants respectfully request reconsideration and withdrawal of the outstanding Office Action rejections based on the foregoing amendments and following remarks. Claims 29 and 31 have been amended. No new matter has been added.

Interview Summary

Applicants' representative contacted Examiner Maewall on March 21, 2011 to inquire as to the inclusion of independent claim 31 in the listing of claims rejected under 35 U.S.C. § 112, second paragraph, without explanation of its defects and to inquire as to the Examiner's comments regarding the clarity of withdrawn claim 56.

With regard to claim 31, the Examiner stated that the inclusion of claim 31 in the listing was likely based on the potential for interpretation of the claim that if the alkaline medium is a gel, it may also read on either of the first and second gels. Applicants suggested amending claim 31 so that the composition contain three components, wherein the first component is an alkaline medium, the second component is a first gel comprising gelatin and phosphate ions, and the third component is a second gel which is free of phosphate ions, which is capable of covering a first layer of the first gel with a layer of this second gel. The Examiner agreed that this amendment appeared to clarify the claimed composition.

With regard to claim 56, the Examiner stated that the comment in the Office Action was a mistake and that there was no need to respond to this comment.

Accordingly, agreement was reached with the Examiner to withdraw her comments with regard to claim 56 and that Applicants' silence as to the propriety of these comments are not, in any way, an acquiescence thereto.

Response to Rejections under § 112

Claims 29-34, 36-49, 51 and 52 remained rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner maintains that the claims are not clear because it is not clear how the composition subsections are different from each other, i.e., for example the composition of claim 29 can contain components (a) and (d), wherein (a) is an alkaline medium (a gel or a solution) comprising calcium ions and (d) is a solution containing calcium ions. Thus, the Examiner asserts that these components can be the same, thereby not clearly defining the metes and bounds of the invention. Applicants submit that claim 29, as amended, clearly defines component (a) as a pre-treating alkaline medium comprising calcium ions that is separate from the growth-promoting solution containing calcium ions, which is a growth-promoting component. Thus, claim 29 now even more fully satisfies the requirements of the second paragraph of 35 U.S.C. § 112. Accordingly, favorable reconsideration and withdrawal of this rejection are respectfully requested. Claims 30, 32-34, 36-49, 51 and 52 depend from claim 29 and should be free of the rejections under § 112, 2nd paragraph, for at least the same reasons.

Similarly, independent claim 31 has been amended to recite a multi-component composition for growing biomimetic enamel-like apatite, fluoroapatite or dentine on tooth material, comprising i) an alkaline pre-treating component comprising calcium ions, (ii) a first gel comprising gelatin and phosphate ions, and (iii) a second gel which is free of phosphate ions, which is capable of covering a first layer of the first gel with a layer of this second gel, wherein said second gel is effective for locally separating reactive ions in said composition to effect said growth of biomimetic enamel-like apatite, fluoroapatite

or dentine on said tooth material. Applicants respectfully submit that claim 31 now even more fully satisfies the requirements of the second paragraph of 35 U.S.C. § 112. Accordingly, favorable reconsideration and withdrawal of this rejection are respectfully requested.

Response to Rejections under § 103

Claims 29-34, 36-38, 48, 49, 51, and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raaf et al. (U.S. 4,397,837) in view of DiGiulio (U.S. 4,080,440). The Examiner asserts that Raaf discloses two-part compositions, one comprising a soluble calcium and the second comprising a soluble phosphate, which may be a gel, a paste, or a solution (col. 2, lines 43-44), for the remineralization or inhibiting demineralization of teeth. The Examiner asserts that Raaf discloses thickeners (col. 4, line 13), including carboxymethylcellulose and carageenate, as well as glycerol (examples) and asserts that gelatin is a thickener (citing to U.S. 4,474,750) and that gelatin was used in Raaf. The Examiner further asserts that Raaf discloses a third layer that optionally comprises a fluoride component (col. 6, lines 3-10), which can be interpreted as meaning that this third layer can also be free of fluoride. The Examiner acknowledges that Raaf does not disclose an alkaline medium, but asserts that DiGiulio discloses that the use of slightly alkaline supersaturated calcium phosphate solutions effect some degree of enamel remineralization (col. 1, lines 45-48 and Example 1). Thus, the Examiner asserts that it would have been obvious to combine Raaf with DiGiulio to arrive at the presently claimed invention. With regard to our arguments, the Examiner states that she has interpreted that absent of indication of a specific medium under (a), the calcium ions will read on subsection (d). Further, the Examiner contends that solutions containing calcium will be inherently alkaline. Thus, the Examiner maintains that Raaf discloses a composition containing [calcium]/[phosphate]/[fluoride] layers compared to the present claim is drawn to a composition comprising [alkaline calcium]/[phosphate]/[no phosphate or calcium] layers

and that DiGiulio suggests use of 10% NaOH thereby remedying the alkaline first layer deficiency in Raaf. Applicants respectfully disagree and traverse the rejections.

Firstly, Applicants submit that claims 48 and 49 require that the second gel be free of fluoride ions. Therefore, the combination of Raaf and DiGiulio does not disclose or suggest the composition of claims 48 and 49. Accordingly, Applicants respectfully request that the rejections of these claims be withdrawn.

Further, the Examiner states that, because Raaf discloses more than two layers, one of ordinary skill would envisage applying a layer with only gel (Office Action, page 11, lines 14-16). Applicants submit that this statement is incorrect, totally based on hindsight, and a mischaracterization of the disclosure of Raaf. The relevant disclosure in Raaf states:

> It is also possible to manufacture solid preparations, such as chewing gum, bonbons or dragees, with more than two layers, in such a way that alternately a calcium compound or a phosphate compound and, optionally, a fluorine compound, are incorporated into each layer, so that, on chewing or sucking, calcium ions, phosphate ions and, optionally, fluoride ions, are released from the various layers.

Col. 6, lines 3-10 of Raaf.

The above-quoted disclosure only describes a solid preparation that can alternately contain calcium, phosphate, and fluoride compounds, wherein a compound is incorporated into **each** layer. There is no disclosure or suggestion in Raaf of a layer comprising only gel as the Examiner contends. This is a critical feature of the present invention. It is clear that the prior art has failed to recognize the claimed feature of having a protective second gel over the first gel in order to form enamel-like apatite, fluoroapatite, or dentine on tooth material. Applicants note that on page 13, 1st full paragraph, of the Office Action, the Examiner mentions that our arguments regarding

the biomimetic principles have not been taken into consideration because these features are not recited in the claims. Accordingly, claim 31 has been amended to recite such features. Thus, claim 31 is drawn to a multi-component composition for growing biomimetic enamel-like apatite, fluoroapatite or dentine on tooth material, comprising

(i) an alkaline pre-treating component comprising calcium ions,

(ii) a first gel comprising gelatin and phosphate ions, and

(iii) a second gel which is free of phosphate ions, which is capable of covering a first layer of the first gel with a layer of this second gel, wherein said second gel is effective for locally separating reactive ions in said composition to effect said growth of biomimetic enamel-like apatite, fluoroapatite or dentine on said tooth material.

With regard to Applicants' argument that DiGiulio discloses that the pH must be kept less than 5, the Examiner asserts that the reference as a whole must considered and not just preferred embodiments. Applicants respectfully request that the Examiner not dismiss this argument without due consideration. Applicants submit that DiGiulio emphasizes that it is essential to keep the pH low throughout that patent specification, including the abstract, Summary of the Invention, Description of the Invention, working examples, independent claim 1, and dependent claim 2. In fact, there is no mention of pH above 5.2 anywhere in the application. Moreover, the reference to 10% NaOH does not describe the amount of NaOH used in the formulation. **Rather, 10% NaOH is the concentration of the stock from which NaOH is drawn** and subsequently used in Example 1. Thus, the composition of Example 1 of DiGiulio contains 0.45% of the 10%

NaOH solution in the cationic half of the composition. Therefore, the composition taught by DiGiulio only contains 0.1 x 0.5 x 0.45 = 0.0225% NaOH and has a pH of 3.0. *See* col. 9, lines 8-9). Accordingly, DiGiulio expressly states that 1 gram of each of the two pastes is placed in the mouth and that the teeth are then cleaned with a toothbrush in the usual manner. *See* col. 9, first paragraph. The cationic part of this solution has a pH of about 3, despite the addition of sodium hydroxide. *See* compositions in the Table in col. 8 and also column 9. Example 2 clearly shows that the pH of the anionic and cationic portions of the composition are both acidic, being pH 2.70 and 3.95, respectively. Moreover, the cationic composition of Example 2 of DiGiulio contained calcium, but its pH was only 3.95. Thus, the Examiner's assertion that a medium comprising calcium would, by nature, have a pH between 6 to 8 is clearly misguided as evidenced by DiGiulio. For this same reason, claims 33 and 34 are not rendered obvious by the combination of cited art because the only pH disclosed therein is 5.2 or lower, which is less than 7.1 to 14 as recited in claim 33, and the amount of NaOH disclosed is 0.0225%, which is less than 0.05 to 1N as recited in claim 34.

Further, the combination of Raaf and DiGiulio does not suggest a composition containing a pre-treating alkaline medium and a composition comprising first and second gels and a solution containing calcium ions. Accordingly, neither reference discloses or suggests using mixed phases as presently claimed.

The Examiner also states again that the components (a) and (d) of claim 29 could be construed identically. Applicants submit that claim construction should be based on the gist of the invention, which is to have separate components, i.e., a pre-treating component, and separate reactive growth-promoting components that are

applied separately and successively. Thus, while component (a) is a pre-treatment component, the component formerly referred to as (d) is a separate growth-promoting component that provides calcium ions for diffusion through the protective gel into the first gel. Accordingly, Applicants submit that no combination of the cited art suggests the claimed composition.

In view of the foregoing, Applicants respectfully submit that the independent claims patentably define the present invention over the citations of record. Further, the dependent claims should also be allowable for the same reasons as their respective base claims and further due to the additional features that they recite. Separate and individual consideration of the dependent claims is respectfully requested.

Claims 38 and 51 remained rejected under 35 U.S.C. § 103(a) as being unpatentable over Raaf in view of DiGiulio, and further in view of Wiedemann (U.S. 6,010,684). The Examiner acknowledges that Raaf and DiGiulio do not disclose the pH of the compositions, but asserts that Wiedemann discloses two part compositions comprising phosphate ions in one part and calcium ions in the second part for the remineralization of teeth (col. 1, lines 11-20). The Examiner contends that Wiedemann discloses that the phosphate part has a pH of 3.0 to 6.5 and the calcium part has a pH of 3.0 to 7.0, so that, when combined, the combination yields a pH from 2.0 to 5.0 (col. 1, lines 59-67) resulting in deep remineralization. The Examiner asserts that this disclosure, in combination with Raaf, renders claims 38 and 51 obvious because it would have been obvious to have adjusted the pH of each component in Raaf and DiGiulio motivated by the desire to obtain the deep remineralization effects shown in Wiedemann. Further, the Examiner asserts that Wiedemann discloses that the

compositions can also contain fluoride ions in the phosphate portion (col. 2, lines 10-19). With regard to Applicants' argument that Wiedemann does not disclose a multiphase system and that it does not remedy the deficiencies of Raaf and DiGiulio, the Examiner asserts that Wiedemann was only cited for its disclosure of pH and thus the rejection is proper and maintained. Applicants submit that the foregoing amendments and arguments are believed to obviate the rejections of independent claim 29, over the combination of Raaf and DiGiulio. Because Wiedemann does not remedy the deficiencies of the combination of Raaf and DiGiulio with regard to claim 29, claims 38 and 51, which depend therefrom, are believed to be non-obvious for at least the same reasons.

Claims 39-47 remained rejected under 35 U.S.C. § 103(a) as being unpatentable over Raaf in view of DiGiulio, and further in view of Barth et al. (U.S. 2007/0154411). The Examiner acknowledges that Raaf and DiGiulio do not disclose fluoroapatite or particle size, but asserts that Barth discloses using fluoroapatite, hydroxyapatite, calcium hydrogen phosphate, and calcium fluoride as remineralization-promoting agents, in amounts from 0.1 to 10% by weight (paragraphs [0061] and [0062]) and particle size from 1 to 200 microns (paragraph [0042]). The Examiner asserts that it would have been obvious to use the remineralization promoting components of Barth in the compositions of Raaf and DiGiulio. Applicants submit that the foregoing amendments and arguments are believed to obviate the rejections of independent claim 29, over the combination of Raaf and DiGiulio. Because Wiedemann does not remedy the deficiencies of the combination of Raaf and DiGiulio with regard to claim 29, claims

39-47, which depend therefrom, are believed to be non-obvious for at least the same reasons.

Claims 29-34, 36-38, 48-49 and 51-52 remained rejected under 35 U.S.C. § 103(a) as being unpatentable over Ebner (DE 3303 937) in view of Singh (U.S. 2003/0152528) and further in view of DiGiulio. In response to our arguments based on the biomimetic principles involved in the present invention and the lack of guidance for combining the disclosures of Ebner, Singh and DiGiulio, the Examiner cites to *In re Keller* for the holding that one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. The Examiner asserts that it would have been obvious to incorporate slightly alkaline supersaturated calcium phosphate solutions to effect enamel remineralization (based on DiGiulio) into the apatite-forming composition of Ebner in order to effect better and more effective remineralization, which the Examiner contends is the same as apatite formation. Applicants respectfully disagree and traverse the rejection. Applicants submit that the Examiner has not responded properly to the arguments that the combination of references is improper and unworkable. Rather, the Examiner has ignored the argument that the combination is improper and unworkable and dismissed the arguments based on a citation to *In re Keller*, which is not relevant caselaw to a traversal of proprieties of a combination of cited references. Further, and in accordance with the previously ignored arguments, MPEP 2143.01(V) and (VI) provide that where a proposed modification or combination of prior art renders the prior art unsatisfactory for its intended purpose or changes the principle of operation of a reference the modification or combination would not be obvious. An obviousness rejection is

improper when the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." *In re Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959). Thus, it is clear that the modifications to Ebner asserted by the Examiner would change the principle of operation of Ebner and are, therefore, improper.

Moreover, the foregoing amendments to independent claims 29 and 31 obviate the rejections based on Ebner in view of Singh and further in view of DiGiulio. No combination of the cited references, even if it could have been made, discloses or suggests a pre-treating alkaline component. While DiGiulio states that the prior art suggested using slightly alkaline calcium phosphate, there is no suggestion to use a pre-treating alkaline medium. DiGiulio is also a poor reference based on the above analysis and should be withdrawn. In view of the foregoing, Applicants respectfully submit that the independent claims patentably define the present invention over the citations of record. Further, the dependent claims should also be allowable for the same reasons as their respective base claims and further due to the additional features that they recite. Separate and individual consideration of the dependent claims is respectfully requested.

Claims 39-47 remained rejected under 35 U.S.C. § 103(a) as being unpatentable over Ebner in view of Singh, DiGiulio, and further in view of Barth. The Examiner acknowledges that Ebner, Singh and DiGiulio do not disclose fluoroapatite or particle size, but asserts that Barth discloses using fluoroapatite, hydroxyapatite, calcium

hydrogen phosphate, and calcium fluoride as remineralization-promoting agents, in amounts from 0.1 to 10% by weight (paragraphs [0061] and [0062]) and particle size from 1 to 200 microns (paragraph [0042]). The Examiner asserts that it would have been obvious to use the remineralization promoting components of Barth in the compositions of Ebner, Singh, and DiGiulio. Applicants submit that the foregoing amendments and arguments are believed to obviate the rejections of independent claim 29, over the combination of Ebner, Singh, and DiGiulio. Because Barth does not remedy the deficiencies of the combination of Ebner, Singh, and DiGiulio, with regard to claim 29, claims 39-47, which depend therefrom, are believed to be non-obvious for at least the same reasons.

Claims 38 and 51 remained rejected under 35 U.S.C. § 103(a) as being unpatentable over Ebner, Singh, DiGiulio, and further in view of Wiedemann (U.S. 6,010,684). The Examiner acknowledges that Ebner, Singh, and DiGiulio do not disclose the pH of the compositions, but asserts that Wiedemann discloses two part compositions comprising phosphate ions in one part and calcium ions in the second part for the remineralization of teeth (col. 1, lines 11-20). The Examiner contends that Wiedemann discloses that the phosphate part has a pH of 3.0 to 6.5 and the calcium part has a pH of 3.0 to 7.0, so that, when combined, the combination yields a pH from 2.0 to 5.0 (col. 1, lines 59-67) resulting in deep remineralization. The Examiner asserts that this disclosure, in combination with Ebner, Singh, and DiGiulio, renders claims 38 and 51 obvious because it would have been obvious to have adjusted the pH of each component in Ebner, Singh, and DiGiulio motivated by the desire to obtain the deep

remineralization effects shown in Wiedemann. Further, the Examiner asserts that Wiedemann discloses that the compositions can also contain fluoride ions in the phosphate portion (col. 2, lines 10-19). With regard to Applicants' argument that Wiedemann does not disclose a multiphase system and that it does not remedy the deficiencies of Ebner, Singh, and DiGiulio, the Examiner asserts that Wiedemann was only cited for its disclosure of pH and thus the rejection is proper and maintained. Applicants submit that the foregoing amendments and arguments are believed to obviate the rejections of independent claim 29, over the combination of Ebner, Singh, and DiGiulio. Because Wiedemann does not remedy the deficiencies of the combination of Ebner, Singh, and DiGiulio, with regard to claim 29, claims 39-47, which depend therefrom, are believed to be non-obvious for at least the same reasons.

Conclusions

In view of the above amendments and remarks hereto, Applicants believe that all of the Examiner's rejections set forth in the March 2, 2011 Office Action have been fully overcome and that the present claims fully satisfy the patent statutes. Applicants, therefore, believe that the application is in condition for allowance.

The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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